IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 17-205-CFC
	)	
ACTAVIS ELIZABETH LLC, ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	)	[redacted] [redacted] **REDACTED - PUBLIC VERSION**
	)	
Defendants.	)	

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTIONS TO EXCLUDE THE EXPERT TESTIMONY OF DRS. VELLTURO, FLEISCHER, MATHIOWITZ, AND DAVIES

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Dated: December 28, 2018

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NATURE AND STAGE OF THE PROCEEDINGS

This is a patent infringement case in which the Orexo Plaintiffs accuse certain of Defendants' generic Suboxone® and Subutex® tablets of infringing U.S. Patent No. 8,454,996 (the "'996 patent"). (D.I. 1.) The patent claims have been construed. (*See* 11/15/2018 Oral Order; *see also* D.I. 118.) Fact discovery is complete, save for an outstanding issue regarding the replacement of one of Defendants' fact witnesses. The parties have exchanged expert reports and the experts have been deposed. Trial is scheduled for March 25, 2019. (D.I. 154.) Defendants now move under Fed. R. Evid. 702 to preclude Orexo from presenting at trial certain unreliable opinions during any needed trial.

SUMMARY OF ARGUMENT

Orexo offers four experts—Drs. Christopher Vellturo (damages), Nicholas Fleischer (regulatory affairs), Edith Mathiowitz (infringement), and Martyn Davies (infringement and validity)—whose opinions are unreliable, speculative, and irrelevant to the issues at hand, and will only serve to confuse and mislead the jury. Therefore, their opinions and testimony should be excluded pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

STATEMENT OF FACTS

Orexo filed this patent infringement lawsuit on February 28, 2017, almost four years after Actavis launched its accused generic Suboxone® product in 2013, and two years after the launch of generic Subutex® in 2015.

I. ACTAVIS'S ACCUSED PRODUCTS

Actavis's accused generic Suboxone® and Subutex® Products (collectively, "Actavis's ANDA products" or "Actavis's accused products") are sublingual tablets containing the active ingredient, buprenorphine, and are used to treat opioid dependence. The tablets are administered sublingually (under the tongue) where the drug can be absorbed directly through the sublingual mucosa into the blood. Actavis's generic Suboxone® tablet was approved by FDA on February 22, 2013, and its generic Subutex® was approved on February 19, 2015. Actavis's ANDA products are bioequivalent to brand Suboxone® and brand Subutex®.

Orexo makes and sells a different product called Zubsolv®. Zubsolv® also contains buprenorphine and is used to treat opioid dependence. Zubsolv® was approved by FDA on July 3, 2013, long *after* the brand Suboxone® and Subutex® products were approved in 2002. Actavis's products are ***not*** generic versions of Zubsolv®.

II. THE '996 PATENT

The '996 patent issued in June 2013 (after the launch of Actavis's generic Suboxone® product) and is directed to a method of administering a sublingual tablet containing buprenorphine. (Ex. 1, '996 patent, claims 1-2.) [redacted]

[redacted]

III. THE HYPOTHETICAL NEGOTIATION

As is standard in assessing patent damages, the parties' experts evaluated a hypothetical negotiation between Orexo and Actavis, which would have occurred in June 2013 just prior to first infringement. The hypothetical negotiation would have resulted in Orexo granting a ***non***-exclusive license to Actavis to use, in its ANDA products, the invention claimed in '996 patent, in the ***United States market***, through expiration of the patent in September 2019. (Ex. 2, Vellturo Opening ¶73-76.) And the result of the negotiation would have been compensation to Orexo in the form of a running royalty as a percentage of net revenues of Actavis's accused products through September 2019. (*Id.*)

However, the parties' experts contest the size of the reasonable royalty that would have been agreed upon. Dr. Vellturo, Orexo's damages expert, rests his opinion on an analysis [redacted] Based on his analysis, [redacted]

[redacted] In contrast, Dr. McDuff, Actavis's damages expert, primarily relies on a reasonable royalty that is based on the cost difference between making Actavis's accused products using the '996 patent, and making Actavis's products in a way that does not infringe the '996 patent. Dr. McDuff, [redacted]

ARGUMENT

I. THE OPINIONS OF OREXO'S DAMAGES EXPERT, DR. CHRISTOPHER VELLTURO, SHOULD BE EXCLUDED BECAUSE HIS REASONABLE ROYALTY ANALYSIS IS UNRELIABLE.

Orexo bears the "burden of proving damages." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). Any testimony Orexo offers to carry this burden must be the product of "reliable principles and methods" and it must "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702; *Daubert*, 509 U.S. at 589. In the context of patent damages, the Court must exercise "its gatekeeping authority to ensure that only theories comporting with settled principles of apportionment [are] allowed to reach the jury." *VirnetX, Inc. v. Cisco Systems*, 767 F.3d 1308, 1328 (Fed. Cir. 2014).

Dr. Vellturo's opinions should be excluded for two reasons. First, in a violation of black letter law, Dr. Vellturo did not apportion his damages to capture the "incremental value that the patented invention" ***of the '996 patent*** adds to Actavis's ANDA products. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014). [redacted]

A. Dr. Vellturo's opinions should be excluded because he did not apportion for the value of the '996 patent.

Dr. Vellturo fails to apportion the incremental value that the claimed invention in the '996 patent adds to Actavis's ANDA products. For more than 125 years, the law has required that damages be specifically apportioned to the patented invention at issue. As the Supreme Court ruled in 1884, "[t]he patentee . . . must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features, and such evidence must be reliable and tangible, and not conjectural or speculative." *Garretson v. Clark,* 111 U.S. 120, 121 (1884). And as the Federal Circuit repeatedly held, "'[t]he essential requirement' for reliability under *Daubert* 'is that the ultimate

reasonable royalty award must be based on the incremental value that the patented invention adds to the end product.'" *Commonwealth Sci. & Indus. Research Organisation v. Cisco Sys., Inc.,* 809 F.3d 1295, 1301 (Fed. Cir. 2015); *Ericsson, Inc.,* 773 F.3d at 1226; *LaserDynamics, Inc. v. Quanta Computer, Inc.,* 694 F.3d 51, 67 (Fed. Cir. 2012); *Uniloc USA, Inc. v. Microsoft Corp.,* 632 F.3d 1292, 1316 (Fed. Cir. 2011); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 904 F.3d 965, 978 (Fed. Cir. 2018). For violating this most fundamental rule, Dr. Vellturo's opinion should be excluded as unreliable under *Daubert*. *Virnetx, Inc.*, 767 F.3d at 1328; *Bio-Rad Laboratories, Inc. v. 10X Genomics, Inc.*, 2018 WL 4691047, *8 (D. Del. Sept. 28, 2018) (excluding expert opinion for failure to apportion damages).

Dr. Vellturo makes two excuses for circumventing the long held requirement that patent damages be tied to the incremental value added by the claimed invention to Actavis's accused products. Both fail, are unreliable, and contrary to well-established law. Dr. Vellturo cannot escape centuries old law intended to ensure that any damages awarded in this case "reflect the value attributable to the infringing features of the product, and no more." *Ericsson, Inc.,* 773 F.3d at 1226.

1. [redacted]

Not one of Dr. Vellturo's purported [redacted] deal with the value of the '996 patent alone, [redacted]

[redacted] Dr. Vellturo does not make any attempt to determine the value of the '996 patent [redacted].

In fact, he testified that ***"no additional apportionment was needed"*** to isolate the value of the '996 patent from the [redacted] He baldly asserted (without substantive analysis) that [redacted] (*Id.*) (emphasis added). When questioned at his deposition, Dr. Vellturo argued that no apportionment was needed because:

[redacted] Dr. Vellturo's argument is legally incorrect and would swallow wholesale the law of apportionment.

First, the blanket exception that Dr. Vellturo advocates is contrary to well established apportionment law. As this Court has held, "a patentee may not argue that prior licenses granting rights to entire portfolios of patents are comparable to a license that the parties would have negotiated for a single asserted patent." *AVM Techs., LLC v. Intel Corp.*, 2013 WL 126233, at *3 (D. Del. Jan. 4, 2013) (Andrews, J.); *Trell v. Marlee Elecs. Corp.*, 912 F.2d 1443, 1446–47 (Fed. Cir. 1990) (damages in a single patent case may not be based on a prior license that "encompassed the right to other inventions" and not just a single patent). But that is precisely what Dr. Vellturo does in this case – he skirts apportionment by vaguely relying on "commercialization" to equate the value of the '996 patent to the value [redacted] That is wrong. [redacted] "[I]t is not enough to merely show that the [claimed invention] is viewed as valuable, important, or … essential to the [product's] use," or even "that a [product] without [the invention] would be commercially unviable." *LaserDynamics, Inc.*, 694 F.3d at 68; *see VirnetX*, 767 F.3d at 1327. Rather, "'[t]he essential requirement' for reliability under *Daubert*" is that any damages analysis "must be based on the incremental value that the patented

invention adds to the end product.'" *Commonwealth Sci. & Indus. Research Organisation,* 809 F.3d at 1301.

Dr. Vellturo, by his own admission, [redacted]

Nevertheless, there is nothing in Dr. Vellturo's expert reports that even attempts to isolate the value of the claimed invention from the unclaimed technologies and features of Actavis's products, [redacted] This, alone, is reason enough to exclude Dr. Vellturo's opinion as contrary to black letter law. *Virnetx, Inc.,* 767 F.3d at 1329 (vacating damages award because expert witness "failed to apportion value between the patented features and the vast number of non-patented features contained in the accused products."); *Sprint Communications Company L.P. v. Comcast IP Holdings*, LLC, 2015 WL 410342,

*2 (D. Del. Jan. 29, 2015) (excluding expert witness for failing to apportion incremental improvements attributable to the patented invention).

2. [redacted]. Vellturo's contorted logic has no legal or factual support and should be excluded as totally unreliable.

First, Dr. Vellturo cites no literature, authority, treatise, or case law to support his naked assertion that [redacted] (Ex. 4, 178:3-179:21.) The sum total of his disclosed analysis consists of one sentence of pure *ipse dixit*. (Ex. 3, ¶95.) *M2M Sols. LLC v. Enfora, Inc.*, 167 F. Supp. 3d 665, 678 (D. Del. 2016)

(excluding expert witnesses on patent damages whose opinions were "nothing more than ipse dixit.")

[redacted]

[redacted] That failure to apportion for the value of the '996 patent violates black letter law and his opinions must be excluded. *Ericsson, Inc.*, 773 F.3d at 1226, *Uniloc*, 632 F.3d at 1318, *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, 2015 WL 1303643, at *4 (D. Del. Mar. 20, 2015) (excluding expert witness for failing to apportion).

[redacted]

In order to use license agreements to assess damages, the patentee "must show that the prior licenses are truly comparable to the license that the parties would have negotiated for the asserted patent before introducing this evidence to the jury." *AVM Techs., LLC*, 2013 WL 126233, at *3. The patentee cannot "rely on license agreements that were radically different from the hypothetical agreement under consideration to determine a reasonable royalty." *Uniloc USA, Inc.*, 632 F.3d at 1316. The Federal Circuit has "stressed that comparisons of past patent licenses to the infringement must account for the technological and economic differences between them." *Wordtech Sys., Inc v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1320 (Fed. Cir. 2010) (vacating damages award because licenses relied on in support were not sufficiently comparable to the hypothetical negotiation).

"When relying on licenses to prove a reasonable royalty, alleging a loose or vague comparability between different technologies or licenses does not suffice." *LaserDynamics, Inc.*, 694 F.3d at 79-80 (holding district court erred denying *Daubert* motion "where comparability between [evidence on licensing program] and a hypothetical license . . . was absent"). Most critically, "[t]he testimony of a damages expert in a patent suit who relies on non-comparable licenses in reaching his royalty rate ***should be excluded***." *DataQuill Ltd. v. High Tech Computer Corp.*, 887 F. Supp. 2d 999, 1022 (S.D. Cal. 2011) (emphasis added) (excluding expert under *Daubert* because license agreements relied on were not "economically comparable to the license that would be reached at the hypothetical negotiation"). Dr. Vellturo's opinions must likewise be excluded here.

[redacted]

[redacted]

1 [redacted]

[redacted]

[redacted]

2. [redacted] hypothetical negotiation.

Dr. Vellturo "has failed to establish economic comparability" between this case [redacted], and his testimony must be "excluded on this ground alone." *DataQuill Ltd.*, 887 F. Supp. 2d at 1023. [redacted] "radically different from the hypothetical agreement under consideration to determine a reasonable royalty." *Uniloc USA, Inc.*, 632 F.3d at 1316.

[redacted]

LaserDynamics, Inc., 694 F.3d at 77 (observing that litigation settlement agreements are viewed dubiously in comparison to a license reached at a hypothetical negotiation); *AVM Technologies, LLC v. Intel Corp.*, 927 F. Supp. 2d 139, 142-43 (D. Del. 2013) (expert's reliance on a litigation settlement agreement as a comparable license without analyzing the underlying litigation rendered expert's opinion "completely speculative"); *M2M Sols. LLC,* 167 F. Supp. 3d at 678 (excluding expert witness who relied on litigation settlement agreements that arose in a "drastically different backdrop than the hypothetical negotiation involving two wiling licensors.")

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Georgia–Pacific Corp. v. United States Plywood Corp., 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970) ("[t]he amount that . . . the patentee . . . and infringer . . . would have agreed upon . . . ***if both had been reasonably and voluntarily trying to reach an agreement***"); *Lucent Techs., Inc.*, 580 F.3d at 1324–25 (describing the hypothetical negotiation as the ***"willing licensor-willing licensee approach"***). [redacted] *Trell*, 912 F.2d at 1447 ("The district court's apparent failure to consider the fact that the Bewator license was exclusive and that it encompassed the right to other inventions compels reversal.")[3]

[redacted]

[redacted]

[redacted]

Here, [redacted] only a running royalty would result from the hypothetical negotiation [redacted]

[redacted]

[redacted]

[redacted]

Uniloc USA, Inc., 632 F.3d at 1316; *M2M Sols. LLC*, 167 F. Supp. 3d at 678 (excluding expert witnesses whose opinions on the comparability of license agreements were "nothing more than ipse dixit."); *Golden Bridge Technology v. Apple Inc.*, 2014 WL 2194501, *6 (N.D. Cal. May 18, 2014) (excluding expert's opinion for failing to establish comparability between license agreements and hypothetical negotiation).

[redacted]

[redacted]

3. [redacted] Damages in a single patent case may not be based on a prior license that "encompassed the right to other inventions." *Trell*, 912 F.2d at 1446–47.

[redacted]

[redacted] Dr. Vellturo's damages opinions are speculative, arbitrary and unreliable, and should be excluded.

II. DR. NICHOLAS FLEISCHER'S OPINIONS ARE UNRELIABLE AND SHOULD BE EXCLUDED.

Dr. Nicholas Fleischer, a "regulatory affairs" expert, offers an opinion that relates to the availability of non-infringing alternatives in support of Orexo's damages position. His opinions also should be excluded.

A. [redacted].

It is axiomatic that damages must "associate [the] proposed royalty with the value of the patented [invention]," and "[a]ny evidence unrelated to the claimed invention does not support compensation for infringement but punishes beyond the reach of the statute." *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010). This includes improper evidence related to patent "hold-up value," which has no relation to the value of the underlying invention. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1209, 1233, 1235 (Fed. Cir. 2014). [redacted]

In this case, non-infringing alternatives bioequivalent to Actavis's accused products were in existence and available well before the issuance of the '996 patent. This is important in calculating damages because "[t]he economic relationship

between the patented method and non-infringing alternative methods, of necessity, would limit the hypothetical negotiation." *Riles v. Shell Expl. & Prod. Co.*, 298 F.3d 1302, 1312 (Fed. Cir. 2002).

Orexo, however, seeks to ignore those facts and inflate its damages award [redacted]. To support its high royalty rate [redacted], Orexo relies on Dr. Fleischer to assert [redacted]. But [redacted] regulatory delay has no bearing on the value of the invention of the '996 patent. *Ericsson*, 773 F.3d at 1209, 1233, 1235.[5] [redacted]

[5] The Federal Circuit previously refused to affirm a damages analysis relying on FDA regulatory delay related to developing a non-infringing product. In *AstraZeneca*, the Federal Circuit did not defend the district court's "consider[ation of] regulatory delay, which applies to every drug application and bears no relation to the value of" the patented invention. *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1335 (Fed. Cir. 2015). Instead, the Federal Circuit affirmed on other grounds, finding that because the accused infringer's "prospect of developing its own non-infringing alternative was bleak, with or without a period of FDA delay, . . .[t]he district court's consideration of the regulatory delay … had no effect on the court's damages calculation." *Id.*

[redacted] But as the Federal Circuit has made clear, damages "must be based on the incremental value that the patented invention adds to the end product." *Ericsson*, 773 F.3d at 1226. The Federal Trade Commission agrees and explains the concept this way:

> A reasonable royalty damages award that is based on high switching costs, rather than the ex ante value of the patented technology compared to alternatives, overcompensates the patentee. It improperly reflects the economic value of investments by the infringer rather just than the economic value of the invention.

(Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* 190 (Mar. 2011).) In other words, hold-up switching costs have nothing to do with the "incremental value" of the ***invention***.

As such, this Court should disregard Orexo's argument, and exclude Dr. Fleischer's opinion, because it is irrelevant and improper in calculating a reasonable royalty.

B. Dr. Fleischer's opinions are speculative [redacted].

The entirety of Dr. Fleischer's opinions relates to "[redacted] (Ex. 6, Fleischer Opening ¶1; *see also* Ex. 7, Fleischer Rebuttal ¶4.) When another district court was faced with similar opinions from Dr. Fleischer on "whether or not, and when, the Food and Drug Administration would have made complex, discretionary, multi-

layered, case-specific decisions relating to" FDA approval, it excluded his opinions because they were "fundamentally speculative." *Twin Cities Bakery Workers Health & Welfare Fund v. Biovail Corp.*, 2005 WL 3675999, at *4-5 (D.D.C. Mar. 31, 2005). As in that case, Dr. Fleischer's opinions here are "too speculative to forge the chain of causation plaintiffs' proof of damages requires," and should likewise be excluded. *Id.* at *5.

[redacted]

he speculative nature of Dr. Fleischer's opinion is made clear by [redacted]

[redacted]

No amount of experience before the FDA can change the fact that Dr. Fleischer's opinions in this case are a guess—"fundamentally speculative"—as to how and when the FDA would act. As a result, just as another district court has found, Dr. Fleischer's opinions "are not—and cannot be—sufficiently reliable to 'assist the trier of fact to understand the evidence or to determine a fact in issue,' and

that in any event their value is substantially outweighed by the danger of unfair prejudice or misleading the jury." *Twin Cities Bakery*, 2005 WL 3675999, at *4 (quoting Fed. R. Evid. 702; citing Fed. R. Evid. 403). And to the extent Orexo's other experts relied on Dr. Fleischer, their testimony should be similarly excluded. (*See, e.g.*, Ex. 18, Davies Opening ¶244; Ex. 19, Davies Rebuttal ¶568; Ex. 3 ¶¶67-69.)

III. THE TESTIMONY OF DR. EDITH MATHIOWITZ [redacted] ON THE ISSUE OF INFRINGEMENT SHOULD BE EXCLUDED.

One dispute in this case regarding infringement centers on whether [redacted] However, Dr. Mathiowitz's [redacted] is unreliable and will only serve to confuse the jury, [redacted] as required by the Court's claim construction. [redacted]

[redacted] The result was therefore biased in favor of Orexo, [redacted] completely undermines the reliability of her conclusions. [redacted] As such, Dr. Mathiowitz's opinions are not the product of "reliable principles and methods" and do not "reliably appl[y] the principles and methods to the facts of the case," and should therefore be excluded. Fed. R. Evid. 702; *Daubert*, 509 U.S. at 589.

A. Dr. Mathiowitz's [redacted]

[redacted]

1. [redacted]

[redacted]

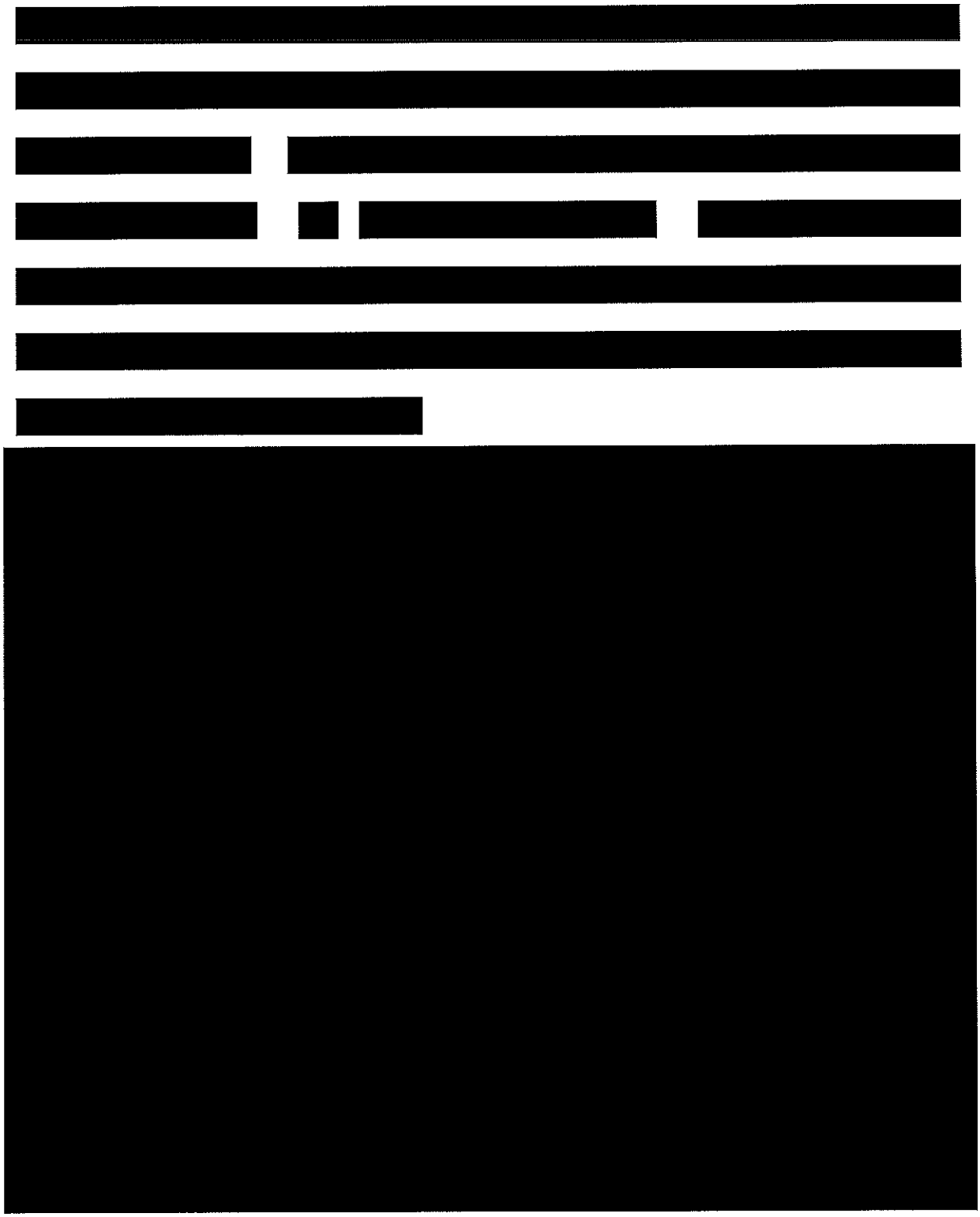
[redacted]

[redacted], her evaluation does not comport with the usage of the term in the '996 patent and construed by the Court. [redacted]

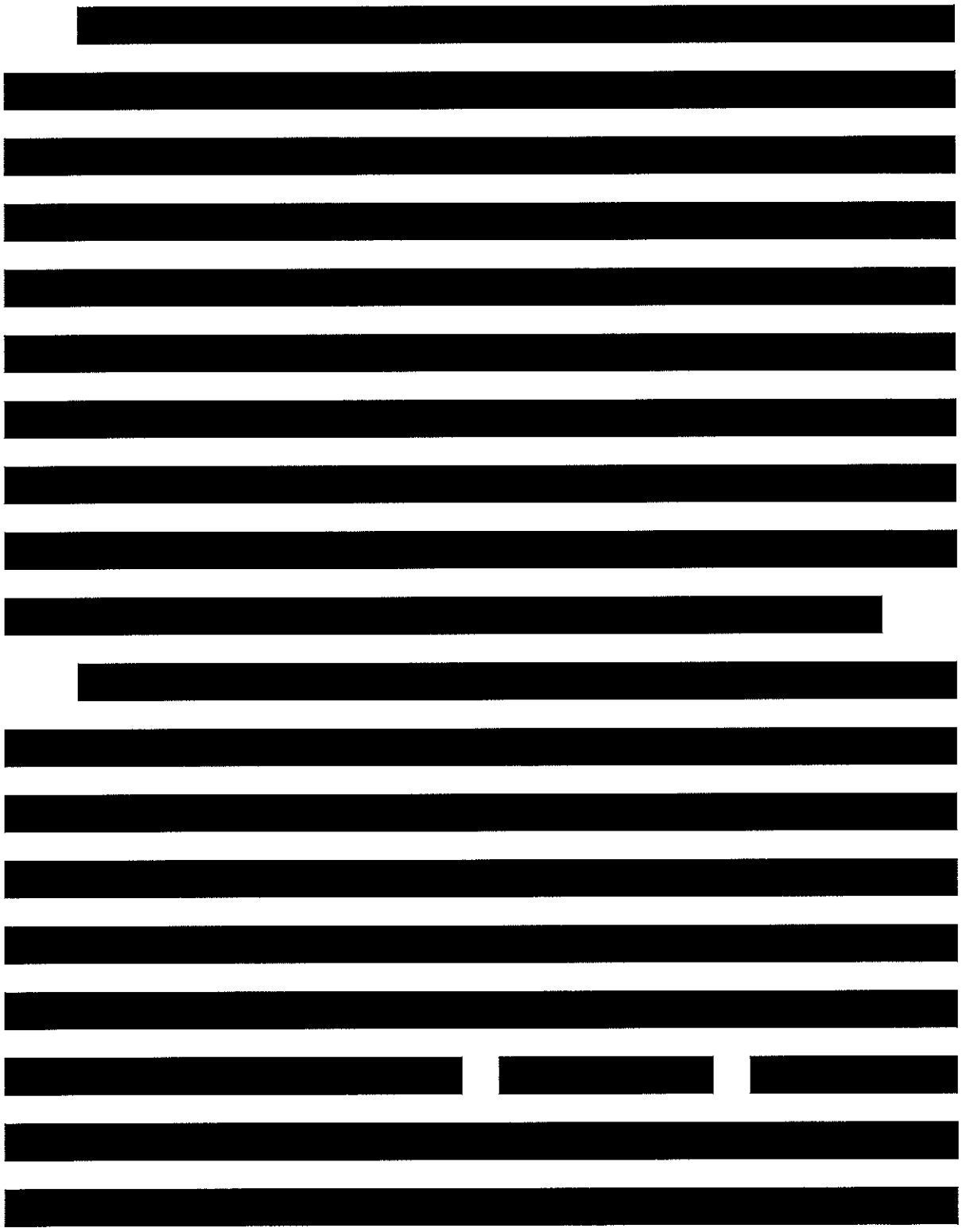
2. [redacted].

[redacted] In short, her [redacted] does not allow her to reach the conclusion that she did.

[redacted]



(*Id.*)



[redacted]

3. [redacted]

[redacted]

Fortunately, the '996 patent directs the public to a particular test (the "Sala" method) to determine whether a dosage form has bio/mucoadhesion promoting properties within the meaning of the '996 patent. (Ex. 1, 9:17-55.) The Sala method as used in Example 4 of the '996 patent can be used to measure bioadhesive properties by using tissue from the small intestine of a rabbit. (*Id.*) The method measures the detachment of the active ingredient from the tissue by placing the test formulation on the rabbit tissue, allowing it to hydrate, and then running distilled water over the material. The detached active ingredient is collected and measured. (*Id.*) Example 4 of the '996 patent then gives a standard by which to measure the results: If the amount of active pharmaceutical ingredient ("API") removed is less than 50%, one can conclude that the test material is bioadhesive within the meaning of the claimed invention in the '996 patent. (*Id.* at 9:39-55.)

[redacted]

C. Dr. Davies's reliance on the [redacted] of Dr. Mathiowitz should likewise be excluded.

Orexo's expert, Dr. Davies, relies on [redacted] portions of Dr. Davies' opinions that rely on Dr. Mathiowitz's [redacted] should likewise be excluded for the same reasons.

IV. DR. DAVIES'S WILLFUL INFRINGEMENT OPINION SHOULD BE EXCLUDED.

[redacted] He offers opinions regarding Actavis's subjective intent—what Actavis "knew or should have known"—both before Actavis became aware of the '996 patent and ***after*** Actavis became aware of the patent in August 2013 (i.e., its pre-suit knowledge of the patent). (*Id.* ¶¶370-76.) [redacted] entirely unrelated to Orexo's alleged embodiment of the claimed invention (Zubsolv®). (*Id.*

¶¶48, 371.) Dr. Davies's willfulness opinions are not based on any expertise or facts and should be excluded.

A. Dr. Davies's testimony regarding Actavis's subjective intent is impermissible.

Orexo must prove "subjective willfulness," i.e., "proof that the defendant acted despite a risk of infringement that was either known or so obvious that it should have been known to the accused infringer." *WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358, 1362 (Fed. Cir. 2016).

However, "[e]xpert witnesses are not permitted to testify . . . regarding the defendant's intent, motive, or state of mind, or evidence by which such state of mind may be inferred." *AstraZeneca LP v. Tap Pharm. Prod., Inc.*, 444 F.Supp.2d 278, 293 (D. Del. 2006). This is precisely what Dr. Davies hopes to do—impermissibly testify regarding ***Actavis's subjective intent***. His willfulness opinions are not based on "scientific, technical, or other specialized knowledge [that] will help the trier of fact" nor "based on sufficient facts or data." Fed. R. Evid. 702; *Daubert*, 509 U.S. at 590. Dr. Davies's willfulness opinions are speculative, irrelevant, and prejudicial and must be excluded.

B. Dr. Davies has no basis for his willfulness opinion.

[redacted]

[redacted] (*Id.* ¶¶373-74.) [redacted]. Davies cites no evidence (because there is none) that Actavis actually ***knew*** that its ANDA products met the claim limitations in the '996 patent, or that it was "so obvious that it should have been known" at the "time of the challenged conduct."

[redacted] Besides his failure to deal with the fact that Actavis's products were developed about 5 years before the '996 patent issued, Dr. Davies cites no evidence that Actavis had any reason to believe that the '996 patent related ***at all*** to its generic Suboxone® and Subutex® products. In fact, the '996 patent is listed in the FDA's "Orange Book" for Zubsolv® and ***not*** for Suboxone® or Subutex®. (*Id.* ¶48 n.1.)

Dr. Davies makes no effort to connect Actavis's general pre-suit awareness of the '996 patent to the accused products. A party's pre-suit knowledge of the patent is not sufficient by itself to find willful infringement. *Ansell Healthcare Prod. LLC v. Reckitt Benckiser LLC*, 2018 WL 620968, at *6 (D. Del. Jan. 30, 2018).

At bottom, Dr. Davies has no basis to opine on the "knowledge of [Actavis] *at the time of the challenged conduct*." *See Halo*, 136 S.Ct. at 1933. His speculative opinion about Actavis's subjective intent is impermissible, *AstraZeneca*, 444 F.Supp.2d at 293, and will only serve to confuse and mislead the jury. This Court should exclude Dr. Davies's irrelevant willfulness opinion.

V. CONCLUSION

For all of the above reasons, Defendants respectfully request that the Court preclude Orexo from presenting the opinions and testimony of Dr. Vellturo, Dr. Fleischer, and Dr. Mathiowitz, and the willful infringement opinion of Dr. Davies.

Dated: December 28, 2018

Respectfully submitted,

By: */s/ John C. Phillips Jr.*

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